

Memorandum of Understanding
regarding the
Care and Use of Animal Subjects
Between the
University of Florida
and the
Malcom Randall VA Medical Center

The University of Florida (UF) and the Malcom Randall VA Medical Center, Gainesville, Florida (VA) make this agreement pertaining to UF personnel who plan to house and/or use animals at the VA facility and to VA personnel who plan to house and/or use animals at UF.

This agreement also covers animals that will be housed and/or used temporarily at the VA or UF as well as VA funded studies approved for off-site waiver and conducted at UF. The agreement is effective July 15, 2009. This agreement will continue from year-to-year unless the agreement is terminated by either institution in writing at least 60 days in advance of the ending date of this agreement. Either institution may terminate this agreement at any time and regardless of cause on 60 days written notice to the other delivered by hand or by registered mail to the address and person shown below (Section X.4) or such other address for notices as specified in writing. This agreement may be modified or altered in writing and signed by both parties. This agreement is inclusive of all vertebrate animal species.

For the purpose of the agreement, the "UF form" is defined as the UF Animal Use Approval Form. The "VA form" is defined as the VA Animal Component of Research Protocol (ACORP).

By virtue of this agreement, each institution (UF and VA), along with their respective Institutional Animal Care and Use Committees (IACUCs), is obligated to ensure continued compliance with all applicable laws and regulations governing the use of research animals (e.g., USDA Animal Welfare Act (AWA) and PHS Policy for the Humane Care and Use of Laboratory Animals). In this agreement, IACUC is used as a generic term to include the equivalent UF IACUC and the VA IACUC. Each institution will work to maintain the standards required for Association for Assessment and Accreditation of Laboratory Animal Care International (AAALAC) accreditation and will maintain a current Animal Welfare Assurance with the Office of Laboratory Animal Welfare (OLAW) at the National Institutes of Health (NIH).

When personnel elect to house or use animals at either the UF or VA facilities, all interested parties agree to the following arrangements in order to ensure that both parties provide appropriate oversight:

I. Veterinary Care

Both institutions shall provide adequate veterinary care at their respective institutions in accordance with the Animal Welfare Act (Title 9 CFR, Part 2, Subpart C, Section 2.33), the most recent edition of the *Guide for the Care and Use of Laboratory Animals* (*Guide*), currently the 1996 edition, and the VA's professional services contract for veterinary oversight and support in effect. The Veterinary Medical Officer has the authority and responsibility for making determinations concerning adequate veterinary care. Any deviation from the veterinarian's recommendation without prior consultation with the veterinarian constitutes non-compliance as outlined in PHS policy and Animal Welfare Regulations (AWRs). Investigators may not provide clinical treatments of the animals unless it is described in the IACUC approved Animal Care and Use Protocol or directed by the VMO or his/her designee. The IACUC is required to investigate and report such non-compliance to regulatory agencies and the Chief Veterinary Medical Officer.

II. Protocol Review

The necessary forms that all investigators must complete, as well as the necessary IACUC approval process, will be governed by the policies stated in Table 1. If a protocol must be reviewed by both IACUCs, personnel may not initiate the research until both IACUCs approve the protocol. If there are differences not easily resolved between the two IACUCs, the chairpersons of the two IACUCs will meet with the investigator to attempt to resolve the issues. However, both IACUCs must approve the final outcome of the resolution. By this agreement, the UF IACUC agrees to accept as valid the VA form as the policy dictates, and the VA IACUC agrees to accept as valid the UF form as the policy dictates.

TABLE 1: PROTOCOL REVIEW PROCESS

This table describes which IACUC form will be used based on which institution employs the individual.

	UF Employees	VA Employees (VA/NFRE Funds)*
Animals Housed and Used at UF	UF form only. Reviewed by UF IACUC only.	VA and UF forms. Reviewed by VA and UF IACUCs.
Animals Housed and Used at VA	VA form only. Reviewed by VA IACUC only. Approved form sent to UF for release of funds.	VA form only. Reviewed by VA IACUC only.
Animals Housed or Used at both UF and VA	UF Full Review. VA Secondary Review	VA Full Review. UF Secondary Review

*VA employee with offsite waiver can use UF form only for Non-VA funded projects. Dual appointment employees will be treated as if they were 100% employed by the majority employer. In the case of equal employment, the employee will be deemed a VA employee.

Any changes in the ACORP require notification and approval by the IACUC prior to implementation. In cases where both IACUCs reviewed the protocol, written approvals must be obtained from each of the two IACUCs prior to initiating such changes.

III. Personnel Qualifications

The UF and VA IACUCs shall have access to each other's records to the extent permitted by law for the purpose of evaluating the qualifications, experience and training of those who are specifically responsible for the care and use of animals. This may include scientists, research personnel, and animal care technicians. The records to be requested may include Occupational Health and Safety Program documentation.

For any VA funded studies and or studies conducted in VA facilities completion of VA annual training is required. These courses are available at www.citiprogram.org and through the aalas learning library. Additional animal related training and workshops are available through UF and the VA. Both VA and UF research personnel are able to utilize each other's animal-related training opportunities.

IV. Reports

Upon reasonable request and notice, each institution shall provide the other with copies of their PHS Assurance Statements as well as their semi-annual reports as required by OLAW. This includes, but is not limited to, any official correspondence regarding the semi-annual (OLAW) and annual (USDA, AAALAC) reports of animal care and use, as well as any correspondence from AAALAC, OLAW, or the USDA concerning the UF or VA facilities. Each institution will provide the other with the report that is relevant to this agreement.

V. Transport of Animals

The transport of animals from one facility to another must be conducted in accordance with the USDA regulations as specified in the Animal Welfare Act (Title 9 CFR, Part 3, Transportation standards). The VA at this time has no vehicles to transport animals and relies on UF to supply these services.

1. The transport of animals to or from the UF or VA facilities shall be conducted during normal business hours (Monday-Thursday 7 am – 4 pm and Friday 7 am - noon), unless prior arrangements have been made with the appropriate veterinary staff. Animals shall be transported in an appropriate climate-controlled vehicle to the approved designated entry points for each facility. Transport of animals from UF to the VA shall comply with Veterinary Medical Unit policy.
2. The responsible person shall notify the veterinary staff, along with any other appropriate departments, at least 24 hours prior to transporting an animal between facilities. The responsible person shall also notify the veterinary staff of any cancellations or changes in transport plans.
3. In the event of unforeseen emergencies strictly related to the clinical care and well-being of a research animal, personnel may elect to transport an animal from one institution to the other. In such a case, the responsible person must contact the veterinary staff of each facility prior to transport in order to request approval for the transfer and proposed procedure(s). Personnel should document any special arrangements that are made for the clinical care of research animals and forward the documentation to the appropriate IACUC(s) as soon as possible after such transport. In all cases involving a significant change (i.e., increasing the risk to animals), approval must be obtained from the appropriate IACUC(s) as described in Section II – Protocol Review.

VI. Housing

If animals are scheduled to be transported to either facility and will not be returned to the original facility, the responsible person will make housing arrangements with the veterinary staff of the receiving facility according to that facility's policies and procedures. The transported animals must be alert and should not be under the influence of any anesthetics or sedatives, unless permission has been obtained from the veterinary staff of the receiving facility and a qualified person is accompanying the animals en route.

If animals are to be housed temporarily in one facility and will be returned back to the other, the responsible person shall make arrangements with the veterinary staff for special space assignments in advance of the animals' arrival. Returning animals must be housed in the receiving facility in compliance with institution policies governing transport and/or transfer of animals. The veterinary staff is responsible for information and policies regarding vendors, health certificates, and other considerations to prevent cross contamination of the resident animals.

VII. Facility Inspections

At a minimum, the UF and VA IACUCs must conduct facility inspections and program reviews every six months of their respective facilities as required by the AWA and the *Guide*. Documented deficiencies of the AWA or of the *Guide* will be submitted by the IACUC members conducting the inspection to their respective IACUCs for correction/action along with deadline dates for these actions.

Semi-annual program reviews and facility inspections are the responsibility of the respective institutions' IACUCs, with formal reports being submitted to the Institutional Official as required by OLAW and the *Guide*. These reports will be maintained in both the offices of the IACUCs and the respective Institutional Officials.

VIII. Use of Hazardous Agents

The use of infectious agents, toxic chemicals, or radioisotopes requires the prior written approval of the respective Subcommittee for Research Safety, the Radiation Safety Committee and/or the Environmental Health & Safety office of the institution whose IACUC approved the protocol. Notification of such use must be given to the veterinary staff attending such animals.

This Memorandum of Understanding is not intended to restrict or otherwise reduce the effectiveness or responsibility of the committees mentioned above (or other committees) to carry out their respective charges, especially as it relates to cooperative animal research projects between the VA and UF. As a result, UF's EH&S (Biosafety) office may still have input into UF projects conducted at the VA. Similarly, VA's Subcommittee for Research Safety may have input into VA projects conducted at UF.

IX. Reports of Non-Compliance

Each institution shall be responsible for notifying the other of any instance of non-compliance with respect to the care or treatment of animals that are involved in UF or VA sponsored research in a timely manner. The UF IACUC shall be responsible for resolving any reports of non-compliance involving animals while en route to or while housed at UF. The VA IACUC shall be responsible for resolving any reports of non-compliance involving animals while en route to or while housed at the VA. If a case of non-compliance has been verified (after a formal or informal investigation), the responsible IACUC shall submit a written report describing the circumstances and subsequent resolution to their respective Institutional Official as required by the AWA and the *Guide*. Information of all verified non-compliance issues should be shared by both institutional IACUCs so that an effective review of related policies and procedures can be done as proof of ongoing institutional self-monitoring.

X. Emergencies

There may be times when the lack of personnel, equipment, or space becomes a major problem for one institution to resolve. This Memorandum of Understanding is intended to help facilitate the resolution of such emergencies rather than to be restrictive. Towards that end the following practices have been used in the past and can continue in the future with the mutual agreement of both parties. Responsible parties here are the Supervisors, Managers, Directors and veterinary staffs of the institutional animal facilities at the VA and UF.

1. Equipment failures: Depending on the equipment, down time, and projected repair time, arrangements can be made to share such items as long as the resident animal populations are not put at risk of contamination.
2. Personnel absences: Depending on the person, reason for absence, and projected time of return to duty, arrangements can be made to share personnel for the sole purpose of animal care. There is no provision here to supply data gathering support or personnel for any research effort. The emergency here is for the direct care of animals until the depleted staff can be returned to normal strength.
3. Space shortages: Depending on what space is short or what species is involved and for the projected time of the shortage, arrangements can be made to temporarily house animals for each other until the space shortage is relieved. Space or room shortages could exist under major power failures, floods, etc. where space becomes unsuitable to house animals or certain species.
4. Notices: Written notices of termination shall be delivered by hand or by registered mail to the Institutional Official (00), thru the Associate Chief of Staff for Research (151) Malcom Randall VA Medical Center, 1601 S.W. Archer Road, Gainesville, FL 32608-1197 or to the Vice President for Research, c/o University of Florida, 2233 Grinter Hall, P.O. Box 115500, Gainesville, FL 32611-5500 as the Institutional Official for the University of Florida.

This agreement is accepted and executed by the parties below as of the day and year first written.

North Florida/South Georgia Veterans
Health System

University of Florida

Thomas R. Cappello 11/23/09
Institutional Official Date
Thomas Cappello, MPH, FACHE
Medical Center Director

Winfred M. Phillips 11/23/09
Institutional Official Date
Winfred M. Phillips, D.Sc.
Vice President for Research

Address:

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